

RemarksClaim objections

The Examiner objected to Claim 13 because the word “is” was missing between “coating” and “selected”. Applicants have amended Claim 13 to include the missing word.

The 102 Rejections*The Berger reference*

The Examiner rejected Claims 1 and 16 under 35 USC 102(b) as being anticipated by U.S. Patent 4,470,975 (the Berger reference).

Claims 1 and 16 of the present application include the step of directly delivering an effective amount of a water-absorbent polymer to the intestinal tract. One means for direct delivery can be, for example, through the use of an enteric coating surrounding the water-absorbent polymer, as described on page 8, lines 15-18 of the present application. Additional examples of direct delivery, as described on page 8, lines 23-26, include: introduction using an enema, a tube that is placed through the nose or mouth and empties directly into the desired portion of the intestine, a tube surgically implanted through the abdomen that empties into the intestine, and via colonic lavage administration.

The Berger reference teaches mixing a polysaccharide polymer with food and administering the polysaccharide-food mixture to animals (Examples 1 through 4 on columns 5-6). The polysaccharide in the Berger reference is thus administered directly to the stomach, not the intestinal tract. The Berger reference does not teach or suggest directly delivering a water absorbent polymer to the intestinal tract, neither through the use of an enteric coating, nor by any other means. As described in Example 3 of the present application, gastric administration, as taught by Berger, interferes with normal absorption of nutrients. Moreover, as described in Example 5 of the present application, gastric administration, as taught by Berger, interferes with removal of metabolic wastes.

For these reasons, Claims 1 and 16 are not anticipated by the Berger reference.

*The Samejima reference*

The Examiner also rejected Claims 19-27 under 35 USC 102(b) as being anticipated by EP 0077956 (the Samejima reference). The Samejima reference describes the possibility of incorporating a water swellable polymer material into an enterically-coated microcapsule containing an active core material, in order to promote release of the active compound. The Samejima reference does not teach or suggest that the active material itself is a water absorbent polymer. By contrast, the claimed invention utilizes a water absorbent polymer as the active ingredient. Therefore, Claims 19-27 of the present invention are not anticipated by the Samejima reference.

*Polycarbophil*

The Examiner rejected Claims 1 and 16 under 35 U.S.C. 102(b) as being anticipated by Polycarbophil. As described on page 6, lines 4 through 8 of the present application, Polycarbophil absorbs 60 times its weight in water, but only 6 times its weight in physiological saline. Applicants have amended Claims 1 and 16 to point out that the water absorbent polymer utilized in the present invention must absorb at least 10 times its weight in physiological saline. Therefore, Claims 1 and 16, as amended, are not anticipated by Polycarbophil.

The 103 Rejections

The Examiner rejected Claims 1-27 under 35 USC 103(a) as being unpatentable over Watts (WO 95/35100) in view of Berger et al. (US Patent No. 4,470,975) or Imondi et al. (U.S. Patent No. 4,143,130). Applicants respectfully disagree with the rejection for the following reasons.

*The Watts reference*

Watts teaches a colonic drug delivery composition comprising a starch capsule containing a drug and being coated such that the drug is predominantly released from the capsule in the colon. Watts does not teach or suggest that the drug in the capsule can be a water absorbent polymer. Nor does Watts teach or suggest removing fluid from the intestinal tract.

The capsules used in Watts have a fairly high water content, at 12 to 16%, as described on page 4, line 24. Such capsules would not be effective for use with a water absorbent polymer because the water that is present in the capsules would be absorbed by the water absorbent polymer. As a result, the polymer would be prematurely saturated and swollen, and would be unable to absorb fluid in the intestinal tract.

*The Combination of the Watts and Berger references*

As described above, Berger teaches administering a polysaccharide to the stomach. There is no motivation to combine the Watts and Berger references because the capsules described by Watts would not work with a water absorbent polymer, as described in the preceding paragraph. . Therefore, Claims 1-27, as amended, are not obvious in view of the combination of the Watts and Berger references.

*The Combination of the Watts and Imondi references*

Imondi teaches treating kidney stones using a water soluble and swellable polymer. Imondi is concerned with binding calcium and does not teach or suggest binding water in the intestinal tract. There is no motivation to combine the Watts and Imondi teachings because, as described above, the capsules described by Watts would not work with a water swellable polymer. Even if the combination of Watts and Imondi would work, the result would be a polymer coated with an enteric coating that binds calcium, not water. Therefore, Claims 1-27, as amended are not obvious in view of the combination of the Watts and Imondi references.

Conclusion

Based on the foregoing amendments and remarks, Applicants respectfully request reconsideration. Applicants submit that the present application now stands in condition for allowance and request early notification thereof.

Respectfully submitted,

Elisabeth T. Jozwiak

Elisabeth T. Jozwiak

Registration No. 41,101

Phone: (989) 636-2880

P. O. Box 1967

Midland, MI 48641-1967

7 May 2003

ETJ/tw